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EXPERIMENTAL USE OF AN ELECTRONICALLY CONTROLLED PROSTHESIS AS AN AUXILIARY LEFT VENTRICLE

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Extracorporeal mechanical assistance to the failing circulation has been attempted in many ways: veno-arterial pumping(1), left-heart bypass without thoracotomy(2), diastolic augmentation(3, 4), postsystolic augmentation(5), intra-arterial baloon pumping(6), and counterpulsation(7). A paracorporeal mechanical pump which partially maintained left-ventricle bypass for about two days(8), and a pump implanted in the left chest which achieved similar results for about 44 hours(9) were recently reported.

Intracorporeal mechanical assistance to the heart, described by Kantrowitz and McKinnon in 1959(10), utilized the motor power of a hemidiaphragm in the dog. The muscle with its vascular supply and phrenic nerve intact, when wrapped around the aorta and electrically stimulated during each diastole, furnished partial left ventricular function. An electronically controlled prosthesis, based on this intracorporeal system, has been developed. It acts as an auxiliary left ventricle, in an attempt to lighten the work load of this chamber. A criterion for accomplishment of this aim, besides diminution of left ventricular peak pressure, was reduction of the recorded area under this pressure curve with use of the auxiliary ventricle.

DESIGN OF THE PROSTHESIS

Experiments were conducted on 28 mongrel dogs to develop an appropriate prosthesis for implantation. After numerous materials had been tested, patency appeared to be best assured by a Silastic bulb* with woven Teflon cuffs+. The first prostheses were hand made. A 20 cm. length of Penrose drain was closed at one end. Two 2-3 cm. Teflon cuffs were placed on the drain 6-7 cm. apart. The tube between the cuffs was distended by introducing water. Silastic was applied in layers to this "mold", firmly sealing the cuffs. Upon completion of the vulcanizing process, the drain was emptied and withdrawn, leaving the Silastic bulb. In 10 patency experiments the prosthesis was substituted for 6-7 cm. of the abdominal aorta. Results were considered encouraging. Three animals are alive nine, eight, and five months after implantation. The prosthesis was patent in 3 other animals sacrificed on the 14th, 40th, and 70th postoperative days.

MATERIALS AND METHODS

A Lucite-encased Silastic bulb, designed and constructed in collaboration with the Avco Company, has been used in 30 experiments (Figure 1). Bulbs of 5, 10, and 15 ml. dynamic volume were implanted in various ways and at various sites in the abdominal or thoracic aorta (Figure 2). The "auxiliary ventricle" is driven by compressed air carried from an outside tank by a polyethylene tube. The tank's pressure regulator is set at the desired flow rate. The flow is interrupted by a solenoid valve controlled by a synchronizing device. The R wave from the left ventricle's ECG, picked up by two Teflon-coated electrodes, triggers the solenoid valve (Figure 3). The valve's opening and closing can be individually controlled and precisely timed. The entire pump stroke must be completed before the beginning of the next ventricular systole. Pressures were recorded with the aid of a strain gauge#: left ventricular pressure via a cannula inserted into the apex of the heart while the chest is open; central aortic pressure via a cannula in the carotid; and femoral pressure via a cannula inserted through a small incision in the groin. ECGs were taken simultaneously.

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* Medical Silastic RTV 382.

+Edwards' Woven Teflon Arterial Graft, 5/16 i. d.

#Statham Strain Gage, Model P 28Db.

In some experiments pressures were recorded from within the prosthesis, and the timing signal was recorded to determine the delay and duration of the stroke.

RESULTS

In three of the first five experiments a 5 ml. dynamic volume bulb was implanted in the abdominal aorta. There was no appreciable drop in pressure although the shape of the ventricular pressure curve was slightly altered. In the other two dogs the 5 ml. prosthesis was implanted end-to-end in the thoracic aorta. Since left ventricular pressure was reduced by as much as 5%, the bulb's effectiveness appeared to be proportional to its proximity to the heart.

In the next study, a 10 ml. bulb was implanted in the same position in one dog. The pulse pressure in the femoral artery widened markedly--from a high of 120 to 160 mm. Hg, and from a low of 80 to below 40 mm. Hg. To reduce this range, a ball valve was implanted below the Silastic bulb. The lower range of the curve was eliminated, but the pressure peak remained the same. A 10 ml. bulb was then implanted end-to-side in the ascending aorta in three dogs, making a blind loop. Left ventricular pressure dropped an average of 6%, and there was an average decrease of 10% in the planimetrically calculated area underlying the curve during systole. When a 15 ml. bulb was implanted in two other animals, left ventricular pressure dropped an average of 13% and the average area decrease was 18%.

The bulb was implanted end-to-side in the ascending and descending aorta, bypassing the aortic arch, in 15 dogs (Figure 4). With a 10 ml. prosthesis (five animals), left ventricular pressure decreased 11% on the average, and the area decrease was 20%. With a 15 ml. prosthesis (ten animals), left ventricular pressure dropped 28% on the average, maximum 38%, and area decreased by 41% on the average, maximum 61% (Figure 5). Summary of results appears in Table I.

TABLE I

AVERAGE FALL IN LEFT VENTRICULAR PEAK PRESSURE WITH PROSTHESES OF VARIED DYNAMIC VOLUME IMPLANTED AT VARIED SITES

Implantation Site	5 ml. Cases	Volume Fall	10 ml. Cases	Volume Fall	15 ml. Cases	Volume Fall
Abdominal Aorta	3	0%				
Thoracic Aorta	2	5%	1	0%		
Ascending Aorta			3	6%	2	13%
Aortic Arch Bypass			5	11%	10	28%

In four other dogs with the bypass implantation, an attempt was made to induce heart block by temporary inflow-occlusion and cutting of the A-V bundle. Stimuli were applied at 80/min. by means of an external pacemaker and electrodes implanted in the left ventricle. It was hoped that ensuring constant parameters in this way would enable us to determine the most effective delay and length of the signal to the solenoid valve. Three dogs died because of technical errors. In the survivor, a 200 msec. delay alternating with a 100 msec. signal duration proved the most effective (Figure 6).

DISCUSSION

In the foregoing experiments, it was expected that end-to-side anastomosis of the prosthesis and the ascending aorta would be the favored position because of its proximity to the heart. However, the greatest decrease in left ventricular pressure (up to 38%) occurred

* Statham Strain Gage, Model P 28Db.

with the aortic-arch bypass postion. Implantation of a 10 ml. prosthesis end-to-end in the thoracic aorta resulted in widely ranging pulse pressures making this position impractical. Results with implantation of a 5 ml. prosthesis end-to-end in the abdominal aorta were also poor.

For more precise comparison of pressure changes in relation to placement of the prosthesis, and experiment was performed with a 15 ml. bulb in the bypass position. Peak left ventricular pressure was reduced by 24%. When the distal cuff of the bulb was clamped (simulating a blindly anastomosed, ascending-aorta bulb) pressure dropped by 13%. Clamping of the proximal cuff (simulating a descending-aorta bulb) resulted in a 15% reduction. These data suggest that the bypass implant more effectively decreases left ventricular pressure. Furthermore, the auxiliary ventricle does not require artificial valves, which complicate the system and carry the risk of postoperative clotting.

The effective dynamic capacity of the auxiliary ventricle is over 15 ml., representing almost half the average capacity of the left ventricle in dogs. The implanted bulb's augmentation potential appears to depend on its proximity to the heart and therefore its ability to present low pressure, and low impedance to flow, at the aortic valve the moment systolic ejection begins.

Hemolysis, a recurring complication during long-term extracorporeal mechanical assistance to the heart, and even during use of an implanted chest pump for left-heart bypass, would not be a problem with this auxiliary ventricle where mechanical stress to the blood is believed to be minimal. No heparinization was needed with or without pumping.

Left ventricular pressure usually decreases gradually within 10 sec. after the auxiliary ventricle is turned on, returning to the previous level within 20 sec. after it is turned off. During pumping, peak diastolic pressure in the central aorta, which is higher than systolic pressure without pumping, gradually drops to the previous level of the peak systolic pressure within 10 sec. Then during the "off" phase, the low blood pressure rises to the previous level within 20 sec. These slow responses seem to reflect a homeostatic response.

Intraventricular pressure and its duration are quite closely related to the heart's work(7). Cardiac output is reported to remain the same during counterpulsation(11). This paper is concerned only with changes in blood pressure; however, in continuing studies an attempt will be made to show that changes in cardiac output occur with implantation of the auxiliary ventricle in the bypass position. The blood-flow rate in the carotid and coronary arteries will also be measured.

It is hoped that perfection of the prosthesis and implantation technique will make it possible to give intermittent assistance to the impaired left ventricle over long periods of time.

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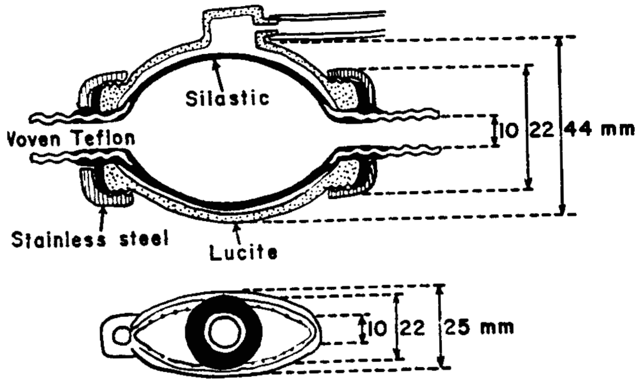

Figure 1. Implantable unit. Lucite case contains Silastic bulb with 3/8" woven Teflon cuffs. Threaded 6 mm. steel cap at each end seals bulb to case. Air compresses bulb which has dynamic volume of 15 ml.

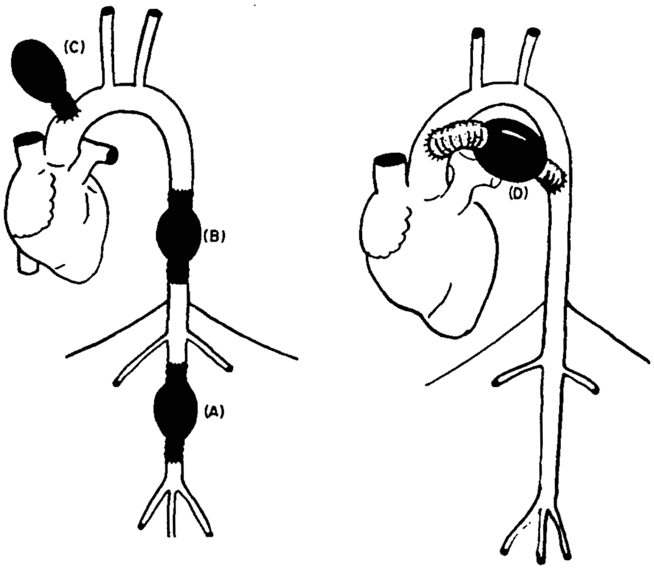

Figure 2. Prostheses were implanted (A) in abdominal aorta; (B) in thoracic aorta; (C) end-to-side, making blind anastomosis with ascending aorta; and (D) end-to-side in ascending and descending aorta, bypassing the aortic arch.

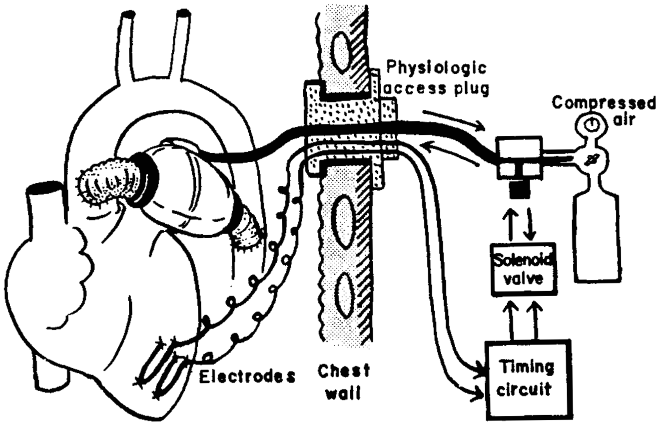

Figure 3. Relation of auxiliary ventricle to heart and aorta. R-wave picked up by implanted electrodes triggers solenoid valve through synchronizing device. Teflon felt body plug permits access of electrodes and air tube through chest wall.

Figure 4. Auxiliary ventricle implanted in bypass position.

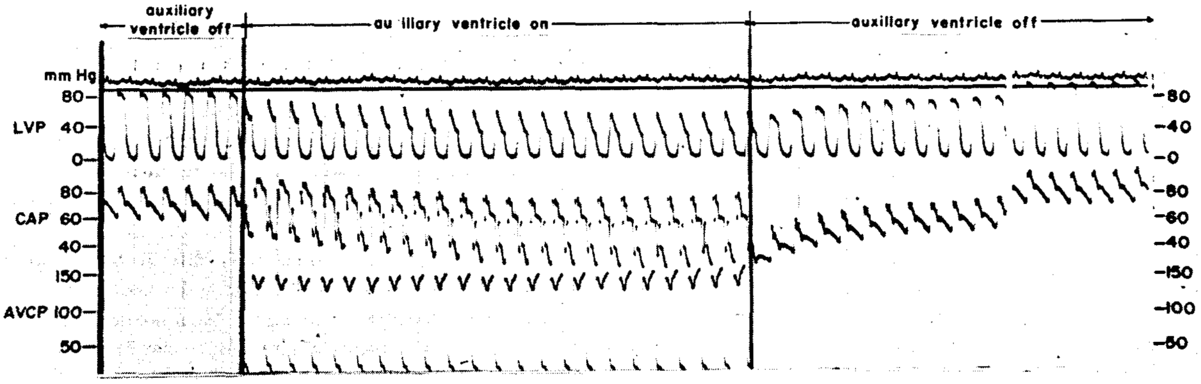

Figure 5. With 15 ml. aortic-bypass prosthesis, left ventricular pressure decreased 38% and area 61% in one dog. Central aortic pressure (CAP) and auxiliary ventricle chamber pressure (AVCP) also shown.

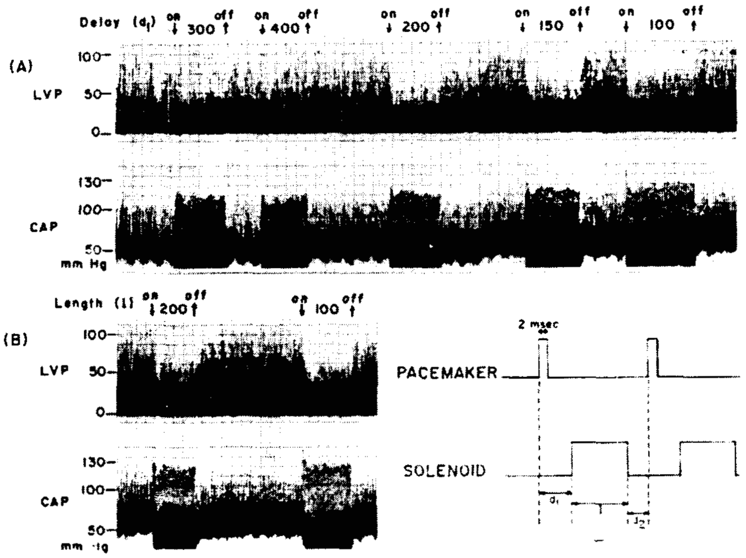

Figure 6. A-V block experiment with 15 ml. auxiliary ventricle in bypass position. Dog's heart is paced at 80/min. by external pacemaker which, after delay (d_1), triggers solenoid valve for variable stimulus length (1). Effect on LVP and CAP of (A) constant solenoid-signal length (300 msec.) and (B) constant delay (200 msec.).

DR. KOLFF: Dr. Kantrowitz has made remarkable progress since he showed his stimulator diaphragm device a few years ago. I warned him then that the flesh was weak, and I felt a little guilty to step on his enthusiasm then.

When I see now, how much progress you have made, I'm kind of glad I told you that the flesh was weak. The other device reminded me of going in a bicycle to the space capsule to the moon, but now you're really in business, and I'm very impressed by this work.

DR. SHAW, New York: How long have these devices been implanted?

Mr. J. KOLFF: Have you noticed any change in heart rate with the activation of this little device?

DR. KOLFF: Would you want to transport that energy in another way inside a chest?

DR. SCHUDER: It is obvious it would be better to transport it by a magnetic means, of course.

DR. KANTROWITZ: I want to thank the gentlemen for their kind remarks.

If moving toward Dr. Kolff's position is progress, then I'm glad I'm making progress.

As far as Dr. Shaw's remark is concerned, in acute experiments, we have had this implanted only for six hours; in chronic experiments, where no compression of the bulb has been carried on, the bulb has been implanted for as long as nine months.

As far as the heart rate is concerned, we have not noticed any change in the heart rate of any appreciable magnitude during the period of time that the auxiliary ventricle is working. As far as Dr. Schuder's remarks are concerned, about the transport of energy, this remains to be seen whether or not it is more efficient to transport the energy through the chest wall via a small tube or electromagnetically. Thank you again.